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STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
WOODWARD, VALERIE LYNN	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DAVID H. FINE and LEE LEICHTER

Appeal 2017-000478
Application 12/541,148
Technology Center 3700

Before LYNNE H. BROWNE, LISA M. GUIJT, and
GORDON D. KINDER, *Administrative Patent Judges*.

BROWNE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

David H. Fine and Lee Leichter (Appellants) appeal under 35 U.S.C. § 134(a) from the rejection of claims 1, 3, 4, 6–12, 27–29, and 31–33. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

CLAIMED SUBJECT MATTER

Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A method of providing a therapeutic amount of nitric oxide to a mammal comprising:
>
> alternating the delivery of one or more breaths of a gas flow including a therapeutic amount of nitric oxide in a carrier gas including oxygen in an amount no less than the amount of oxygen in air to the mammal via a first delivery tube; and
>
> the delivery of one or more breaths of oxygen-enriched air to the mammal via a second delivery tube immediately after the one or more breaths of the therapeutic amount of nitric oxide in the gas delivered via the first delivery tube;
>
> wherein each breath of the one or more breaths of the gas flow and each breath of the one or more breaths of the oxygen-enriched air are delivered at a pre-determined time; and
>
> wherein the one or more breaths of the gas flow and the one or more breaths of oxygen-enriched air are delivered to the mammal in a pre-determined pulsed or intermittent delivery sequence.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Briend	US 5,651,358	July 29, 1997
Heinonen	US 5,918,596	July 6, 1999
Stenzler	US 6,581,599 B1	June 24, 2003
Rounbehler	US 2006/0180147 A1	Aug. 17, 2006
Stenzler	US 2007/0144515 A1	June 28, 2007
Miller	US 2010/0018526 A1	Jan. 28, 2010

REJECTIONS

I. Claims 1, 3, and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Stenzler '515.

II. Claim 4 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Stenzler '515, Stenzler '599, and Heinonen.

III. Claims 6–9 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Stenzler '515 and Stenzler '599.

IV. Claim 12 stands rejected under 35 U.S.C. §103(a) as unpatentable over Stenzler '515 and Briend.

V. Claims 10, 11, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Stenzler '515 and Rounbehler.

VI. Claims 31–33 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Stenzler '515 and Miller.

DISCUSSION

Rejection I

Appellants argue claims 1, 3, and 27 together. *See* Appeal Br. 7. We select independent claim 1 as the representative claim, and claims 3 and 27 stand or fall with claim 1.

The Examiner finds that Stenzler '515 discloses each and every limitation of claim 1. *See* Final Act. 2–3. In particular, the Examiner finds that the gas flow from supply 106 corresponds to the claimed "gas flow including a therapeutic amount of nitric oxide in a carrier gas" and that the delivery from supply 108 corresponds to the claimed delivery of "oxygen-enriched air" as set forth in claim 1. *See id.*; Appeal Br. 14. The Examiner further finds that the diluent gas (i.e. carrier gas) is "air, N_2, O_2, inert gas, or a mixture of these gases." Final Act. 3 (citing Stenzler '515 ¶ 26).

Appellants contend that "[t]he main difference between Stenzler and the claimed invention is that Stenzler's system teaches away from using a

carrier gas including oxygen in an amount no less than the amount of oxygen in air, as recited in claim 1." Appeal Br. 5 (emphasis omitted). However, Appellants' argument that Stenzler '515 "teaches away" from using a carrier gas including oxygen is misplaced because "[t]eaching away is irrelevant to anticipation." *Seachange Intern., Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1380 (Fed. Cir. 2005) (citing *Celeritas*, 150 F.3d 1354, 1361 (Fed. Cir. 1998); *Bristol–Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001).

Noting that claim 1 requires "a therapeutic amount of nitric oxide in a carrier gas including oxygen in an amount no less than the amount of oxygen in air," Appellants further argue that "a skilled person in the art would not consider the concentration of nitrogen in the air or lower concentration than the amount of nitrogen in the air as a 'higher concentration.'" Appeal Br. 6. Thus, Appellants take issue with the manner in which Stenzler '515 differentiates between its two sources of nitric oxide. However, Appellants do not explain why the Examiner's findings that Stenzler '515 discloses "a therapeutic amount of nitric oxide 106" and a carrier gas that is "air, N_2, O_2, inert gas, or a mixture of these gases" are in error. Final Act. 2–3.

Appellants' Specification states that a "therapeutic amount of nitric oxide can be at least 2 ppm and as high as 2000 ppm." Spec. 2. Stenzler '515 states that the amount of nitric oxide in supply 106 is about 80–400 ppm. Stenzler '515 ¶ 22. Thus, Stenzler's supply 106 provides a therapeutic amount of nitric oxide. Further, as the Examiner correctly finds, Stenzler '515 discloses air and pure oxygen as a carrier gases. *Id.* at ¶ 26. Both of which have oxygen "in an amount no less than the amount of oxygen in air," as required by claim 1. Moreover, as noted by the Examiner, "the claim

only requires that the carrier gas contain oxygen in an amount no less than the amount present in air, not that the overall gas mixture including the NO source contain O_2 in a concentration at least that of air." Ans. 4–5. Thus, Appellants' do not apprise us of error.

In addition, Appellants contend that the Examiner misquoted paragraph 26 of Stenzler and relied upon an incorrect hypothetical situation in the Advisory Action. *See* Appeal Br. 6. However, as the rejection does not rely on statements made in the Advisory Action, even if the Examiner did misquote paragraph 26 and made an irrelevant point in the Advisory Action, this is not indicative of error.

For these reasons, we sustain the Examiner's decision rejecting claim 1, and claims 3 and 27, which fall therewith.

Rejection II

The Examiner determines that Stenzler '515 fails to disclose a method wherein "one breath of nitric oxide is delivered for one to six seconds and one breath of oxygen- enriched air is delivered for one to six seconds." Final Act. 4. The Examiner further finds that Stenzler '599 teaches "alternating delivery of an NO containing gas with oxygen enriched air breath by breath." *Id.* (citing Stenzler '599 12:66–13:6; Fig. 4A). In addition, the Examiner finds that "Heinonen teaches inhalation times of one to a couple of seconds (one to six seconds). *Id.* (citing Heinonen 5:36–37). Based on these findings, the Examiner determines that it would have been obvious to modify Stenzler '515's

> method so that one breath of NO is delivered for one to six seconds and one breath of oxygen enriched air is delivered for one to six seconds as taught by Stenzler ('599) and Heinonen in order to produce a sufficient flow profile for effecting a desired

> therapeutic result and which closely follows a normal breathing cycle to efficiently and comfortably deliver gases to the patient.

Id.

Appellants contend that contend that "Stenzler and Stenzler II cannot be combined to teach claim 1 because Stenzler teaches away from using oxygen-enriched air as a second source of gas." Appeal Br. 7. In support of this contention, Appellants argue that "Stenzler teaches that for a second source of gas, it is preferable to use a gas such as N_2 or an inert gas to dilute the NO concentration at lower concentration since these gases will not oxidize the NO into NO_2 as would O_2 or air." *Id.* at 7–8 (citing Stenzler '515 ¶ 26).

With respect to the supply with a lower NO concentration Stenzler '515 states:

> FIG. 1 also shows a source of diluent gas 14 as part of the NO delivery device 2 that is used to dilute the concentration of NO. The source of diluent gas 14 can contain N_2, O_2, Air, an inert gas, or a mixture of these gases. *It is preferable* to use a gas such as N_2 or an inert gas to dilute the NO concentration at lower concentration since these gases will not oxidize the NO into NO_2 as would O_2 or air.

Stenzler '515 ¶ 26 (emphasis added). Thus, Stenzler discloses a preference for N_2 or an inert gas for gas flow with a low concentration of nitric oxide. However, indication of a preferences does not teach away from the non-preferred alternatives. "[A] reference will teach away when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention. A statement that a particular combination is not a preferred embodiment does not teach away absent clear discouragement of that combination." *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005) (internal citations omitted). Here

Stenzler '515 describes the disadvantages of the non-preferred alternatives in some instances, but does not clearly discourage their use. Accordingly, Stenzler '515 does not "teach away" from the proposed combination.

Appellants further argue that "Stenzler II cannot be modified by Stenzler, either." Appeal Br. 8. This argument is not responsive to the rejection as articulated by the Examiner, and thus, does not apprise us of error. In addition, Appellants argue that "[t]his deficiency is not remedied by Heinonen." *Id.* However, as we find no deficiency in need of remedy, this argument is unconvincing.

For these reasons, we sustain the Examiner's decision rejecting claim 4.

Rejection III

The Examiner finds that Stenzler '515 and Stenzler '599 disclose or suggest all of the limitations of claims 6–9. Final Act. 5–6. As the Examiner's findings are similar to those outlined *supra* with respect to the rejection of claim 4, we do not discuss them in further detail.

After essentially repeating the unpersuasive "teaching away" argument discussed *supra*, Appellants argue that "Stenzler cannot be modified by Stenzler II because such modification would change the principle operation of Stenzler, which would render Stenzler unsatisfactory for its intended purpose." Appeal Br. 9. However, Appellants do not identify the principle of operation in Stenzler '515 which would be modified or explain how Stenzler '515 would be rendered unsatisfactory for its intended purpose. *See id.* Thus, Appellants do not apprise us of error.

In addition, Appellants argue that "Stenzler II cannot be modified by Stenzler, either." *Id.* However, as discussed *supra*, this argument is not

responsive to the rejection as articulated by the Examiner, and thus, does not apprise us of error.

For these reasons, we sustain the Examiner's decision rejecting claims 6–9.

Rejection IV

The Examiner finds that Stenzler '515 and Briend disclose or suggest all of the limitations of claim 12. Final Act. 7. In particular, the Examiner finds that Briend teaches supplying a gaseous mixture with between 50 and 100%, of oxygen. *Id.*

After essentially repeating the "teaching away" argument discussed *supra*, Appellants contend that "[t]he deficiencies [in Stenzler '515] are not remedied by Briend." Appeal Br. 11. As we find no such deficiencies, Appellants' argument is unconvincing.

We sustain the Examiner's decision rejecting claim 12.

Rejection V

The Examiner finds that Stenzler '515 and Rounbehler disclose or suggest all of the limitations of claims 10, 11, 28, and 29. Final Act. 7–8. In particular, the Examiner finds that "Rounbehler teaches generating NO and air by passing an air flow having NO2 (in the gas flow) through a surface-activated material coated with an aqueous antioxidant." *Id.* at 7.

After essentially repeating the "teaching away" argument discussed *supra*, Appellants contend that "Rounbehler does not remedy this defect" in Stenzler '515. Appeal Br. 12. As we find no such defect, Appellants' argument is unconvincing.

We sustain the Examiner's decision rejecting claims 10, 11, 28, and 29.

Rejection VI

The Examiner finds that Stenzler '515 and Miller disclose or suggest all of the limitations of claims 31–33. Final Act. 8–9. In particular, the Examiner finds that "Miller teaches a therapeutic amount of NO with a concentration greater than 1000 ppm and less than 2000 ppm." *Id.* at 8 (citation omitted).

After essentially repeating the "teaching away" argument discussed supra, Appellants contend that "Miller does not remedy this defect" in Stenzler '515. Appeal Br. 13. As we find no such defect, Appellants' argument is unconvincing.

We sustain the Examiner's decision rejecting claims 31–33.

DECISION

The Examiner's rejections of claims 1, 3, 4, 6–12, 27–29, and 31–33 are AFFIRMED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED